Caribbean Environmental Protection Division
Multimedia Permits and Compliance Branch

Inspection Report

Inspection Date: December 12, 2018

Facility Name: Steri-Tech Inc.

Facility Address: Road 701 Km. 0.7, Salinas, P.R. 00751

Coordinates: Latitude: 17.971126 Longitude: -66.300420

ICIS-Air ID #: PR0000007211100004

Federal Facility: ☐ Yes ☒ No

Facility size: Minor Operating Source

Completed Activity: PCE

Priority: Core

State Referral: ☐ Yes ☒ No

NAICS code: 561910 – Product Sterilization and Packaging Services

Facility Contact(s): Jorge A. Vivoni Farage, CEO, (787) 824-4040, jorgevivoni@steri-tech.com

Jorge A. Vivoni Ortiz, Vice President and General Manager, (787) 824-4040, avivoni@teri-tech.com

Alvin Arriaga, Operations Manager, (787) 824-4040

EPA Inspector: Alex O. Rivera, Environmental Engineer, 787-977-5845, rivera.alex@epa.gov

Permitted Regulatory Program(s) Reviewed:

Ethylene Oxide Emissions Standards for Sterilization Facilities - 40 CFR Part 63 Subpart O

Pollutant: Ethylene Oxide

I. Facility Background Information[1]

Steri-Tech Inc. ("STI") is a Puerto Rican corporation founded in 1986. STI specializes in contract sterilization of medical devices with ethylene oxide ("EtO") and offer customers laboratory and validation services. STI's distribution network of medical, safety, and clean room apparel, includes many major brands which are stock in a 40,000 square foot facility. STI facility is located at Road 701, Km. 0.7, Salinas Industrial Park, Salinas, Puerto Rico. Figure 1 and 2 provides an aerial view of the facility location.

STI's operates an EtO sterilization process that sterilize products by making an alkylation reaction that eliminates the capability of the microorganisms to reproduce. The sterilization process consists of three (3) main processes: (1) conditioning; (2) sterilization; and (3) aeration. STI specializes in the sterilization of both pharmaceutical products and medical devices. According to STI's website, the sterilization process begins the moment the product to be sterilized arrives to the facility. All products are thoroughly inspected and duly recorded as they enter the facility and are placed in a quarantined warehouse to avoid any contact with products already processed. The product is placed in a pre-conditioning room, where they are prepared for and undergo the sterilization process. The pre-conditioning process allow STI to attain specific limits for temperature and relative humidity prior to the sterilization process. The EtO sterilization requires the control of four (4) parameters: gas concentration, temperature, relative humidity, and time of exposure in the sterilization chambers. STI operates four (4) sterilization chambers that use 100% EtO. Once the products are processed in the sterilization chambers, the product is placed in an aeration room where EtO gas residuals are eliminated to ensure the safe handling of the product.

Figure 1 – Aerial view of the area where Steri-Tech is located obtained from Google Earth Pro®

[1] According to the Steri-Tech Inc. website: http://steri-tech.com/

Figure 2 – Aerial view of the area within 0.50 miles radius of Steri-Tech from Google Earth Pro®

II. Regulatory Background

Under Section 112 of the Clean Air Act ("CAA"), the U. S. Environmental Protection Agency ("EPA") is required to develop national emission standards for hazardous air pollutants ("NESHAP") for source categories that have been identified as major sources of hazardous air pollutants ("HAP"). Section 112(b) of the CAA identifies EtO as a HAP because it is suspected to cause cancer in humans, is highly mutagenic and teratogenic, and has significant acute and sub chronic exposure health effects. To meet the requirements of the CAA, EPA promulgated NESHAP for ethylene oxide commercial sterilization and fumigation operations in the December 6, 1994 *Federal Register* as Subpart O of Part 63 of the Code of Federal Regulations ("CFR"). STI's EtO sterilization process is subject to 40 CFR Part 63 Subpart O. 40 CFR §63.361 defines sterilization facility as any stationary source where EtO is used in the sterilization or fumigation of materials.

Pursuant to the provisions of the Environmental Quality Board (EQB) Regulations for the Control of Atmospheric Pollution (RCAP) and the provisions of the 40 CFR Part 63 Subpart O; STI is authorized to operate a stationary source of air pollutant emissions limited to the units and conditions described in EQB issued operating permit PFE-RG-63-0308-0006-I-II-O ("Permit"), issued on December 10, 2009. The Permit expired on December 10, 2014.

Occupational use and exposure to EtO is regulated by the Occupational Safety and Health Administration (OSHA) under 29 CFR 1910.1047. EtO is also considered a pesticide under Title 7 U.S.C. 136 et seq., Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Emergency Planning and Community Right to Know Act (EPCRA) and the CAA outline the reporting requirements on the use and storage of EtO. The Food and Drug Administration (FDA) reviews the efficacy of EtO in the sterilization of medical devices and approves EtO sterilizers for medical use. The National Fire Protection Association (NFPA) Standard 560, "Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation" requires proper installation of EtO sterilizers and ventilation systems.

III. Facility Air Emission Units

The following is the list of STI emission units included in the Permit with its respective operational and control equipment description[2]:

Emission Source	Emission Control Equipment	Description
1. EtO sterilization chamber #1	Thermal oxidizer (vapor control unit) with a 99% efficiency	Volumetric capacity of 1,080 cubic feet. Consumes 105 pounds per day of EtO.
2. EtO sterilization chamber #2	Thermal oxidizer (vapor control unit) with a 99% efficiency	Volumetric capacity of 1,080 cubic feet. Consumes 75 pounds per day of EtO.
3. EtO sterilization chamber #4	Thermal oxidizer (vapor control unit) with a 99% efficiency	Volumetric capacity of 675 cubic feet. Consumes 50 pounds per day of EtO.
4. EtO sterilization chamber #5	Thermal oxidizer (vapor control unit) with a 99% efficiency	Volumetric capacity of 1,580 cubic feet. Consumes 90 pounds per day of EtO.
5. Aeration room #1	Two (2) Boilers of 30 HP each	Dimensions: 30' x 7.5' x 12'
6. Aeration room #2		Dimensions: 30' x 30' x 12'

[2] According to STI's permit to operate an emission source issued by EQB on December 10, 2009 (PFE-RG-63-0308-00O6-I-II-O)

7. Aeration room #3		Dimensions: 37' x 22' x 12'
8. NAO Thermal Oxidizer (Vapor Control Unit) – Model NVCU-TAC	None	22 feet height and 24 inches of diameter stack. Capacity of 1,08 MMBTU/hr and consumes liquified petroleum gas ("LPG") at a rate of 11.8 gal/hr.
9. Fulton Brand 30 HP Boiler #1	None	25 feet height and 8 inches of diameter stack. Consumes fuel (diesel, kerosene or distilled oil) with a sulfur percent by weight of 0.25% at a rate of 9.33 gal/hr.
10. Fulton Brand 30 HP Boiler #2		
11. Power Generator	None	12 feet height and 6 inches of diameter stack. Capacity of 328.3 HP and consumes diesel fuel with a sulfur percent by weight of 0.4% at a rate of 20 gal/hr.

IV. Inspection Summary

The EPA inspector Alex Rivera (Inspector) arrived unannounced at the facility premises around 9:50 AM. The Inspector was received by Mr. Jorge A. Vivoni Ortiz, Vice President and General Manager of STI. The Inspector showed his enforcement officer credentials and explained the purpose of the inspection. Mr. Vivoni Ortiz explained the Inspector that Mr, Juan Argüelles, was the person in charge of managing the environmental compliance aspect of STI, but he died in July 2018. Mr. Vivoni Ortiz was assigned to perform the duties Mr. Argüelles and explained the Inspector about the need of calling STI environmental consultant at some point to obtain further details about the facility air permit compliance. Mr. Vivoni Ortiz also informed that his dad and STI CEO Mr. Jorge A. Vivoni Farage will arrive at some point to the facility and will join the inspection. The Inspector informed Mr. Vivoni Ortiz that an inspection questionnaire will be followed and if there is any question that requires further explanation or discussion it can be discussed later during the day or when the environmental consultant becomes available. Mr. Vivoni Ortiz the Inspector agreed with proceeding with the inspection questionnaire. Mr. Jorge A. Vivoni Farage arrived and joined the inspection shortly after the inspector started summarizing to Mr. Vivoni Ortiz the contents of the questionnaire and during the discussion of EPA material with background information on EtO and its hazards. The Inspector also provided STI representatives copies of EPA Region 5, October 2017, Factsheet titled Reducing Ethylene Oxide Use.

Inspection Questionnaire

A. Facility General Information

1. The facility started operations in 1986.

2. Ownership changes: Micro-Biotrol Inc, used to operate the facility until 1984. Mr. Jorge A. Vivoni Farage founded STI in 1986.

3. Description of facility historical and current operations: STI has been operating as a contract sterilization provider since 1986. STI no longer have manufacturing process at the facility. STI sterilizes medical devices for around eight (8) clients, none of those clients are hospitals. STI currently sterilizes product only under contract services. According to Mr. Vivoni Farage, the sterilization process is fully automated and is programmed by the sterilization area operators using the system control panel located at the operators control rooms. The facility has two (2) control rooms to manage the facility four (4) sterilization chambers, two (2) chambers are designated to each control room. The sterilization cycle and specific settings (sterilization cycle and degassing requirements) are designated by its clients and varies depending on the product that will be sterilized. The product is received in the facility already packaged by its clients and processed in pallets (48" x 48"x 6" each). Once the product arrives to the facility it is placed in an unprocessed staging area and depending on the product specification, it can either go directly into the sterilization chambers or to a pre-conditioning area. Pre-conditioning consist of humidity control. Humidity is controlled with boiler generated vapor.

   According to Mr. Vivoni Farage, each sterilization chamber is validated prior to begin the sterilization cycle of each specific client product. Each chamber has injection of EtO and humidity. Once the desired pressure is reached, the product begins an EtO dwell to allow product to absorb EtO, during that process the pressure, temperature and time is monitored. Once the dwelling process finalizes, the air washing process begins. Washing will depend in each product validation and consist of generation of vacuum and air injection until reaching atmospheric pressure. The facility has clients that request such air washing process to be done with nitrogen instead of oxygen. The facility has a sample room to verify each sterilization effectiveness. The client establishes biological indicators for their product(s) sterilization cycles that is sent to a private laboratory located in San Germán, PR.

   According to Mr. Vivoni Farage, the facility EtO operators does not enter the sterilization chambers, since the product pallets are entered into the chamber using a finger lift. Mr. Vivoni Farage also informed that each sterilization chamber does not have back vents and that when a sterilization cycle ends the chamber door is opened and is left opened for one (1) hour to allow any residual EtO emissions that remained in the chamber to be released. Mr. Vivoni Farage explained that the building has air blowers that manages the air of the building from east to west of the building. On the west side of the building the facility has blowers to extract the air into the atmosphere. The product is then transferred to the aeration rooms, the facility currently operated three (3) aeration rooms. Each aerations room has a circulation blower that suctions air from atmosphere that is heated using a coil to heat air. The air within the aeration rooms is recirculated, the temperature is maintained around 90 °F to 130 °F. Each room conduct has a baffle to allow part of the recirculation air to reach the one of the boilers. The facility operates one boiler at a time. Once the product is aerated is stored in a staging area where the product is picked up by the client.

4. The facility currently employs 29 employees. The facility has 10 sterilization area operators and two (2) mechanics that provide assistance to the sterilization area.

5. The Inspector asked for a facility layout or diagram. STI representatives provided a copy of a facility layout dated August 13, 2018 to the Inspector. Mr. Vivoni Farage explained and discussed the layout with the Inspector.

6. Facility air emission source operating permit. – STI air emission source operating permit was issued by EQB in 2009 and expired in 2014. According to Mr. Vivoni Farage, STI submitted the required permit renewal application accordingly and are currently waiting for the permit to be finalized. According to Mr. Vivoni Farage, STI had been in communication with EQB about its status. Facility environmental consultant ERM working and following up with permit renewal process.

7. Operational status of the facility emission units described in the facility permit – According to Mr. Vivoni Farage, no changes needed to the emission units currently in the permit.

8. Description of packaging process and how that influences the sterilization cycle and amount of time in the aeration room. – According to Mr. Vivoni Ortiz, the sterilization cycle is determined by client validation processes and will vary by the type of product provided by client. Clients usually have two (2) sterilization providers for redundancy purposes. Clients elaborate a validation process to generate a protocol based on STI's sterilization chambers and aeration rooms. According to Mr. Vivoni Ortiz, an EtO residual study is done for each type of product.

9. Emissions variance throughout the day - STI operates 24/7. Sterilization processes varies due to the amount of product provided by clients. Sterilization fluctuates depending on product demand by each client. Each product is validated by each client to determine the specific sterilization cycle and degassing requirements.

10. Shipping—According to Mr. Vivoni Farage, STI clients are responsible for product logistics. STI only sterilize product, does not provides delivery service for its clients.

B. Emission Limits and Control Techniques

1. The facility is considered an existing source based on the date of commencement of operations (year 1986) provided by the facility representatives.

2. Initial notification - According to Mr. Vivoni Farage, the facility submitted to EPA and EQB an initial notification letter acknowledging the facility applicability to 40 CFR Part 63 Subpart O. An initial notification letter from the facility dated August 4, 1995 was found at EPA's facility files and discussed during the inspection. The letter described the facility operations and indicated that the facility plan to comply with the regulation by December 1997 by installing control equipment to reduce the EtO emissions from the facility.

3. Facility annual EtO consumption – The Inspector asked the facility representatives to provide the facility EtO consumption for two (2) consecutive periods of 12 months. Mr. Vivoni Ortiz stated that such information is available and included in the fuel and chemical consumption reports that the facility submits to EQB in a semi-annual basis. The Inspector requested the facility to provide copies

of the semi-annual reports being submitted to EQB corresponding to the 2nd quarter of 2016, year 2017, and 1st quarter of 2018[3]. According to the facility representatives the average EtO consumption is around 70,000 pounds per year (35 tons/yr).

4. Emission Control Techniques – According to the facility representatives the EtO emissions generated at the sterilization chambers are controlled using a thermal oxidizer fabricated by NAO, Inc. Model NVCU-TAC. According to the facility's Permit the thermal oxidizer unit has a stack of 22 feet of height and 24 inches of diameter. Also, according to the Permit, the unit possess a capacity of 1.08 MMBTU/hr and consumes liquified petroleum at a rate of 11.8 gal/hr. According to Mr. Vivoni Farage, the thermal oxidizer was installed in 1997, and no changes or modifications have been done to the unit since such date. Mr. Vivoni Farage informed the Inspector that a performance test was performed in 1999 and the EtO control efficiency for the emissions of the sterilization chambers and the aeration rooms was determined to be 100%. The Inspector requested Mr. Vivoni Farage to provide an electronic copy of the performance test report[4]. Mr. Vivoni Farage showed the hard copy of the performance test report dated January 2000 and confirmed the results of the test. According to 40 CFR Part 63 Subpart O Table 1 of Section 63.362, the facility shall reduce EtO emissions from sterilization chambers by at least 99% from each sterilization chamber.

   Additionally, the facility representatives explained that even though the facility has the capability of controlling the aeration rooms EtO emissions using the thermal oxidizing unit, the facility requested EPA to use an alternate control device. The facility is controlling the aeration rooms EtO emissions using two (2) 30 Hp boilers (Fulton brand). Mr. Vivoni Farage informed that the facility requested EPA approval of such alternate emission control mechanism through a letter dated August 15, 2001. STI requested the use of the boilers as an emission control mechanism under the argument that the EtO levels at the aeration rooms documented in the performance test were well below the detection limit of 1.2 ppmv without being treated by a control device. Mr. Vivoni Farage showed the Inspector a copy of EPA's response to STI's letter dated December 13, 2001[5] on which EPA granted STI's request to use the facility boilers to control the EtO emissions generated at the aeration rooms. EPA conditioned its approval by requesting STI to seek the modification of its Permit to add the following conditions: the new alternate control mechanism should be added as the aeration rooms EtO emission control technique, to maintain at all times a log to record the total amount of pallets aerated in the aeration rooms to verify that the total amount of pallets are equal or less than the quantity in the worst case scenario used during the most recent performance test performed at the facility. The most recent performance test was performed in November 29th through December2, 1999. According to the performance test report, the total amount of pallets shall be equal or less than 82 pallets. Mr. Vivoni stated that a log book to record the number of pallets aerated at each of the rooms is being kept and the requirement of the number of pallets[6] is being monitored.

   The Inspector requested Mr. Vivoni Farage to provide further details about the purpose of the boilers operation. Mr. Vivoni Farage explained that the purposed of the boilers is to supply vapor to regulate temperature and relative humidity of the sterilization chamber, the aeration and pre-conditioning rooms. Mr. Vivoni Farage added that the boilers vapor is necessary for the operation

[3] STI provided to EPA electronic copies of the semi-annual reports being submitted to EQB corresponding to the 2nd quarter of 2016, year 2017, and 1st quarter of 2018 on January 9, 2019.

[4] STI provided to EPA the electronic copy of the performance test conducted in 1999 on January 24, 2019.

[5] STI provided EPA an electronic copy of the 2001 letter on January 9, 2019.

[6] The Inspector requested copies of the aeration rooms pallets log book corresponding to the months of November 2018, December 2018, and January 2019 via email on February 13, 2019. Those were provided to EPA on February 14, 2019.

of the facility, since they cannot use the pre-conditioning room, the sterilization chambers and aeration rooms without the boilers.

The Inspector asked Mr. Vivoni about the facility back vent emissions and how the facility calculate the amount of back vent emissions. Mr. Vivoni Farage stated that the facility sterilization chambers does not have back vents. Mr. Vivoni Farage explained that during the sterilization process air washes, the excess EtO is extracted with a vacuum pump that conveys the EtO through a manifold to the thermal oxidizer. Mr. Vivoni Farage added that once the sterilization process is done, the sterilization chamber door is opened and left open for a period of one (1) hour to allow any EtO emissions that remained in the chamber to be released.

C. Monitoring Requirements for Sterilization Chambers Vents

1. Control device - According to the information provided by Mr. Vivoni Farage, the facility is using a thermal oxidizer as a control device to meet the 99% EtO emission reduction standard (§ 63.362(c)) from the sterilization chambers vents. According to Mr. Vivoni Farage, the thermal oxidizer was installed in 1997, and no changes or modifications have been done to the unit since such date.

2. Amount of sterilization chambers and sizes – Mr. Vivoni Ortiz informed the Inspector that the facility has four (4) sterilization chambers. According to Mr. Vivoni Farage, no changes or modifications have done to the facility chambers. The following is a summary of the details provided about each chamber:

   #1 (1801) - 1,080 cubic feet – 10 pallets capacity (48" x 48"x 6" each pallet)
   #2 (1802) – 1,080 cubic feet – 10 pallets capacity
   #3 (1804) – 675 cubic feet – 6 pallets capacity
   #4 (1805) – 1582 cubic feet – 16 pallets stacked (8 pallets each stack) – chamber with highest capacity used during performance test.

   The Inspector requested the facility representatives to provide an electronic copy of the EtO consumption rates for each chamber for two (2) consecutives of 12 months for year 2017 and 2018[7]. According to a copy of the facility 2017 Toxics Release Inventory report that the Inspector brought for the inspection, the facility EtO consumption during year 2017 was 68,794 pounds and 79,306 pounds during 2016.

3. Sterilization chambers operating scenarios – According to the facility representatives, the facility uses two (2) sterilization chambers simultaneously in a normal operating scenario. Facility may use up to three (3) chambers simultaneously to manage any unexpected increase of products.

4. Thermal oxidizer site specific operating parameter *(§ 63.363(b)(3))* - According to the January 2000 performance test report provided by Mr. Vivoni Farage during the inspection, the operating parameters values established are the following:

   a. 1,500 °F normal high temperature (set-point) at exhaust point; the baseline temperature established as a result of the three (3) runs conducted during the performance test was 1,521.20 °F.
   b. 1600 °F maximum temperature at exhaust point;

[7] STI provided EPA an electronic copy of the EtO consumption rates from year 2017 and 2018 on January 9, 2019.

c. 0.8 seconds residence time;
d. 258 BTU/cf;
e. 4201 scfh maximum waste gas flow;
f. 18.2" WC maximum pressure drop.

5. Thermal oxidizer temperature monitoring data *(§ 63.364(c) and (§ 63.364(c)(4))* - Thermal oxidizer exhaust point temperature is obtained and documented with a chart recorder. The chart recorder was manufactured by Honeywell Model DR4300 (# TCN-0111). According to Mr. Vivoni Sr. the chart recorder is calibrated at least twice per year. Mr. Vivoni Sr. provided copy of a thermal oxidizer chart recorder calibration form and a quality assurance table with all the equipment that requires calibration at the facility. The Inspector requested Mr. Vivoni Farage to provide a copy of the chart recorder sheet. Mr. Vivoni asked the facility Operations Manager, Mr. Alvin Arriaga to obtain a copy. Mr. Arriaga showed the inspector several examples of the chart recorder sheets that showed that the thermal oxidizer normal operating temperature is 750 °F. The Inspector asked Mr. Arriaga about the thermal oxidizer normal operating temperature and Mr. Arriaga confirmed that the thermal oxidizer normal operating temperature is 750 °F. The Inspector requested the facility representatives to provide electronic copies of the chart recorder sheets corresponding to the months of August 2018, September 2018, October 2018, and November 2018[8].

   According to Mr. Vivoni Farage Mr. Arriaga is in charge of the collecting and replacing the chart recorder sheets. Mr. Arriaga stated that the thermal oxidizer has an alarm that triggers a red-light alarm that can be seen at the thermal oxidizer unit control panel and at the operators control room to allow the operator to shut the unit down if necessary. The sterilization process needs to be shut down manually when the thermal oxidizer goes out of service. According to Mr. Vivoni Farage, such scenario has not occurred.

   Mr. Vivoni Farage provided copy of the most recent calibration sheet prepared by independent calibration company conducted in August 31, 2018. Chart recorder calibration is conducted every six (6) months with a ±10°F instrument tolerance. According to the calibration sheet the temperature recorder did not showed deviations over ±10°F.

   The Inspector asked the facility representatives about how the facility is recording the daily average oxidation temperatures of the thermal oxidizer exhaust point. Mr. Vivoni Farage and Mr. Arriaga informed the Inspector that the facility does not record the daily average oxidation temperature of the thermal oxidizer exhaust point. Mr. Arriaga stated that the facility collects the thermal oxidizer chart recorder strip charts and file each at the operator room but does not record or calculate a daily oxidation temperature average.

6. Thermal oxidizer operation frequency – According to Mr. Arriaga, the thermal oxidizer operates seven (7) days per week and 24 hours per day. The thermal oxidizer in only shut down for maintenance purposes.

D. Monitoring Requirements for Aeration Rooms Vents

1. Amount of aeration rooms - According to Mr. Vivoni Farage, the facility is currently using three (3) aeration rooms. The facility has an additional room that is being prepared to be used as a fourth

[8] STI provided EPA the electronic copies of the thermal oxidizer temperature chart recorder strip charts from the months of August, September, October, and November 2018 on January 24, 2019.

aeration room. The Inspector asked Mr. Vivoni if such changes were approved by EQB. Mr. Vivoni Farage stated that the room will have the same dimensions of the other three (3) rooms and that it was added to the permit renewal package submitted to EQB. The Inspector requested Mr. Vivoni Farage to submit the electronic copy of the permit renewal package submitted to EQB[9].

2. Product aeration times – According to Mr. Vivoni Farage each product aeration specifications are determined by the client and that usually varies from 24 to 72 hours.

3. Control device - The facility is controlling the aeration rooms EtO emissions using two (2) 30 Hp boilers (Fulton brand) as an alternate control device that was approved by EPA as described in Section B.4 above. The EtO emissions are connected to a manifold that conveys the air to the boilers.

4. Alternate control device monitoring data *(§ 63.364(d))* –EPA conditioned its approval of the alternate control device by requesting STI to seek the modification of its Permit to add the following conditions: the new alternate control mechanism should be added as the aeration rooms EtO emission control technique, to maintain at all times a log to record the total amount of pallets aerated in the aeration rooms to verify that the total amount of pallets are equal or less than the quantity in the worst case scenario used during the most recent performance test performed at the facility. According to the performance test report, the total amount of pallets shall be equal or less than 82 pallets. Mr. Vivoni stated that a log book to record the number of pallets aerated at each of the rooms is being kept and the requirement of the number of pallets[10] is being monitored.

   The Inspector asked Mr. Vivoni Farage is a performance test was performed to the boilers. Mr. Vivoni Farage stated that no performance test was performed to the boilers. Mr. Vivoni Farage informed the Inspector that the facility permit also requires the boilers to operate and maintain a continuous stream pressure recorder to document the operation of the boilers. Mr. Vivoni Farage stated that the steam pressure recorder data is also obtained using a chart recorder and that the strip charts data being filed and organized using the same procedures for the thermal oxidizer chart recorder data. Mr. Vivoni Farage also added that the permit requires the steam pressure to be calibrated every six (6) months by an independent calibration company and the facility needs to certify compliance with the steam recorder requirements in the semi-annual compliance reports being submitted to EQB. The Inspector requested the facility to provide copies of the semi-annual reports being submitted to EQB corresponding to the 2nd quarter of 2016, year 2017, and 1st quarter of 2018.

E. Recordkeeping and Reporting Requirements

1. EtO consumption records – According to Mr. Vivoni Ortiz the facility records the EtO consumption in an hourly and monthly basis for each off the facility sterilization chambers. The Inspector requested Mr. Vivoni Ortiz to provide electronic copies of the EtO consumption data corresponding to years 2016, 2017, and 2018[11].

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[9] STI provided EPA an electronic copy of the most recent permit renewal package submitted to EQB dated May 3, 2017 on January 9, 2019..

[10] The Inspector requested copies of the aeration rooms pallets log book corresponding to the months of November 2018, December 2018, and January 2019 via email on February 13, 2019.

[11] STI provided EPA an electronic copy of the EtO consumption rates from year 2017 and 2018 on January 9, 2019.

2. Semi-annual deviations, monitoring systems performance summary reports *(§ 63.366(a)(3))* – The Inspector asked Mr. Vivoni Ortiz about the semi-annual reports that are required by 40 CFR Part 63 Subpart a and Subpart O. Mr. Vivoni Ortiz stated that such semi-annual reports are being submitted accordingly to EQB. The Inspector informed Mr. Vivoni Ortiz that copies of those reports are also required to be submitted to EPA. The Inspector requested Mr. Vivoni Ortiz to provide electronic copies of the semi-annual reports being submitted to EQB corresponding to the 2nd quarter of 2016, year 2017, and 1st quarter of 2018[12].

3. Construction of new sources *(§ 63.366(b))* - The Inspector requested Mr. Vivoni Ortiz to provide electronic copies of the most recent version of the Permit renewal package submitted to EQB to verify if the facility is providing EQB the information about the new aeration room[13]. The review will provide the Inspector an opportunity to verify that all the sources identified during the inspection walkthrough are properly identified in the Permit.

4. Fuel consumption reports – According to the Permit the facility is required to submit to EQB an annual report including the monthly fuel consumption, fuel sulfur content, and the hours of operations of the emergency generators, boilers, and thermal oxidizer. Mr. Vivoni Ortiz stated that the facility is complying with such requirement in accordance with the Permit.

F. Other Information

1. EtO employee exposure survey and monitoring – The Inspector asked the facility representatives about the number of employees exposed to EtO, what mechanisms are in place to monitor EtO concentrations in critical areas and if any EtO exposure surveys have been performed at the facility. Mr. Vivoni Farage stated that the facility has 12 employees that work as sterilization operators and mechanics at the product sterilization processes. Mr. Vivoni Farage also added that the facility does not have any mechanism to monitor the concentration of EtO in the facility. Mr. Vivoni Farage also informed that the facility has not conducted an EtO exposure survey.

2. EtO specific training to employees – The Inspector asked the facility representatives about EtO specific training provided to employees working in sterilization area. Mr. Vivoni Ortiz stated that the facility provides training to employees and has standard operating procedures in place to make sure that the sterilization are processes are performed accordingly.

3. . EtO accidental releases – According to Mr. Vivoni Farage no accidental release has affected the facility and informed the Inspector that the facility has an emergency release plan.

4. The Inspector asked the facility representatives if the facility has any EtO gas detection sensors in the facility. Mr. Vivoni Ortiz stated that the facility is currently in the process of getting quotes to buy EtO sensors, but currently the facility does not have EtO sensors within the facility.

5. EtO supplier – According to Mr. Vivoni Farage the facility EtO supplier is ARC Balchem. Mr. Vivoni Farage added that the facility buys EtO directly from ARC Balchem and Mays Ochoa in Puerto Rico

[12] STI provided to EPA electronic copies of the semi-annual reports being submitted to EQB corresponding to the 2nd quarter of 2016, year 2017, and 1st quarter of 2018 on January 9, 2019.

[13] STI provided EPA an electronic copy of the most recent permit renewal package submitted to EQB dated May 3, 2017 on January 9, 2019.

has a contract with ARC Balchem for EtO delivery to its clients in Puerto Rico. The facility buys an average of three (3) 400 pounds EtO drums in a weekly basis.

6. NAICS code – The Inspector asked the facility representatives about which NAICS code the facility has been using. Mr. Vivoni Ortiz stated that they have struggled to determine the code who better describe the facility current operations. According to Mr. Vivoni Ortiz, they are currently using NAICS code 54199 (All other professional scientific, and technical services). Also, and in accordance with the facility 2017 TRI report, the facility used NAICS code 339112 (Surgical and Medical Instrument Manufacturing). The Inspector offered assistance to the facility representatives to verify which NAICS code will be the most representative.

7. TRI Reporting – Mr. Vivoni Ortiz is the person currently responsible for preparing the TRI Form R report. Mr. Vivoni Ortiz agreed on adding the NAICS code more applicable to their current operations. The Inspector asked Mr. Vivoni about the facility EtO emissions being reported. Mr. Vivoni Farage stated that the facility does not report EtO emissions because the thermal oxidizer offers 100% EtO reduction efficiency.

8. Sterilized product management – According to Mr. Vivoni Farage once the product is removed from the aeration rooms, it is placed in a staging area while the product waits for shipping. The product can be hold in this area from two (2) to three (3) days. The Inspector asked the facility representatives about the product post sterilization EtO residual requirement. According to Mr. Vivoni Ortiz, the product sterilized in the facility does not have any EtO residual requirement and the product placed in the staging area should not have any EtO residual.

9. EtO emissions calculations – According to Mr. Vivoni Ortiz the EtO emissions calculations are prepared by STI's environmental consultant who is working with the Permit renewal process. The Inspector requested the facility to provide electronic copies of the EtO emissions calculations[14].

G. Facility Walkthrough

1. The Inspector ended the discussion of the inspection questionnaire at 4:45 PM and proceeded with facility walkthrough along with facility representatives Mr. Vivoni Farage, Mr. Vivoni Ortiz and Mr. Arriaga.

2. The facility was not sterilizing at the time of the walkthrough.

3. The processed product area is ventilated with blowers to keep the area ventilated and the air flowing from east to west of the facility towards several extractors that in turn convey the air to the atmosphere.

4. The Inspector was escorted outside where the aeration rooms blowers are located. According to Mr. Arrieta, when the product is placed in an aeration room, it can contain around 2-3% EtO residual. EtO residual is reduced to zero at the aeration rooms, according to Mr. Arrieta. Each aeration room has a blower to keep the air recirculating and to regulate the room temperature. Mr. Arrieta explained that the air is heated with a coil.

[14] STI provided EPA an electronic copy of the most recent permit renewal package submitted to EQB dated May 3, 2017 on January 9, 2019.

5. The group went to the area of the thermal oxidizer were according to Mr. Arrieta, the thermal oxidizer was operating under normal conditions at a temperature of around 750°F. The oxidizer has a panel to control pilot flame, water level and EtO emission valves status. The panel also has an alarm to identify a thermal oxidizer malfunctioning issue. The thermal oxidizer burns liquified propane gas. The facility has two (2) propane bullet tanks of 500 gallons each located adjacent to the thermal oxidizer.

6. The Inspector was escorted to the area where the facility has a nitrogen tank of 1,500 gallons. Mr. Vivoni Farage explained that the facility already installed a system that will allow STI to generate its own nitrogen. The system has not been used yet.

7. The Inspector requested to go to the area where the boilers are located. The facility has a boiler room where the two (2) boiler units are located. The following is the information gathered from each:

    a. Boiler #1:

        i. Model FB-030A
        ii. Installed in 2005
        iii. No. 2 Fuel Oil (diesel fuel)
        iv. 1,035 lbs steam/hr
        v. Unit has a steam recorder and fuel usage recorder

    b. Boiler #2:

        i. Model ICS 30
        ii. Installed in 2017. New unit to replace Boiler No. 2 included in the Permit. Mr. Vivoni Farage did not know if a construction permit was issued to install the unit.
        iii. No. 2 Fuel Oil (diesel fuel)
        iv. 1,035 lbs steam/hr
        v. The unit does not have a steam recorder nor a fuel usage recorder.

8. The facility has a 1,000 gallons diesel storage tank for the two (2) boilers.

9. The Inspector asked the facility representatives if the facility has a windsock to determine the wind direction. The facility representatives stated that the facility does not have a windsock.

10. The Inspector requested the facility representatives to show the area where the EtO drums are stored. The facility representatives showed the Inspector the area where empty and in-use EtO drums are located. The facility uses 400 pounds EtO drums that are property of ARC Balchem Corp. and distributed through Mays Ochoa (Cataño, Puerto Rico). The facility stores the EtO drums outside the facility structure and beneath a galvalume roof with no wall enclosure. The area does not have EtO detection meters and alarm system. The facility has an EtO volatizer for each sterilization chamber.

11. The facility has two (2) emergency power generator to provide back-up power. The facility installed a new emergency generator after Hurricane María that according to Mr. Vivoni Farage will be added to the Permit. The new emergency power generator is located at the western part of the facility (contiguous to PR-701).

12. As shown in Figure 2 above, which shows a 50 miles radius within the facility, the western part of the facility is adjacent to PR-701 and Hacienda Margarita residential area; the southern part of the facility is near the Playa de Salinas residential area; the eastern part of the facility and adjacent to the facility there is a Puerto Rico Fire Department Firefighters academy (fire training academy); and to the northern part of the facility the town of Salinas is located.

13. The Inspector concluded the facility walkthrough at 5:40 PM and proceeded with the inspection closure at STI's conference room.

H. Inspection Closing Meeting

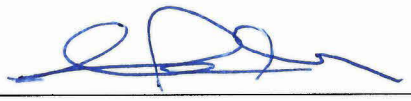
The Inspector met with Mr. Vivoni Farage and Mr. Vivoni Ortiz at STI's conference room to conclude the inspection around 5:45 PM. The Inspector summarized the records and documents that STI needs to provide and informed the facility representatives to submit those electronically. The Inspector agreed with the facility representatives to send an email with the list of documents needed and to create a Sharepoint Site to allow the exchange of documents between EPA and STI. The following is the list of documents requested to be submitted by STI:

1. Documentation showing the Facility EtO usage and consumption for two (2) periods of 12 consecutive months.
2. Copies of semi-annual compliance reports sent to EQB and corresponding to the 2nd quarter of 2016, 2017, and first quarter of 2018.
3. Copies of thermal oxidizer chart recorder graphs for the months of August, September, October and November 2018.
4. Copy of thermal oxidizer performance test report dated January 2000.
5. Copy of most recent version of permit renewal application submitted for the PR Environmental Quality Board review.
6. EPA's letter approving the use of a boiler as the aeration rooms control device.
7. Documentation of calculations to obtain EtO emissions.

The Inspector thanked the facility representatives for their cooperation and availability during the inspection and concluded the inspection around 6:00 PM.

Inspection Report Sign-off

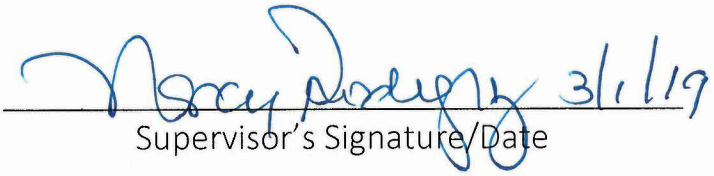
Inspector's Name: Alex Rivera



3/1/19

Inspector's Signature/Date

Supervisor's Name: Nancy Rodríguez



3/1/19

Supervisor's Signature/Date